

August 12, 2005

Dockets Management Branch Food and Drug Administration Department of Health and Human Services Room 1061 5630 Fishers Lane Rockville, MD 20857

Subject:

Amendment to CITIZEN'S PETITION

Ref. # 2005-P-0242

Sterile Vancomycin Hydrochloride, USP Pharmacy Bulk Package, 100 grams Original Filing Date: June 16, 2005

By means of this amendment, the undersigned wishes to change the reference listed drug from Baxter's Vancocin® HCl (Vancomycin Injection, USP) in GALAXY plastic container to Baxter's Vancoled® 10 grams, pharmacy bulk package. The subject of Ref. # 2005-P-0242 differs from Vancoled® in its total dosage strength but not the dosage amount recommended for administration to the patient.

Please note that because of the lack of availability of labeling for Vancoled[®], labeling for American Pharmaceutical Partners' generic product was submitted in its place.

If you have any questions or need additional information, please feel free to contact me.

Sincerely,

SAMSON MEDICAL TECHNOLOGIES, L.L.C.

Marvin Samson

Chief Executive Officer

200SP-0242

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